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AI healthcare companies: navigating the cutting edge of technology with Canada's regulators

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> Hear from prominent industry experts on the state of play and what's next for the sector in our feature Q&As from Abubaker Khalifa of Moonrise Medical, Saumik Biswas of Tenomix and members of Lumira Ventures.

AI has tremendous potential to transform the future of the healthcare industry. The technology's ability to leverage computing power, advanced algorithms and big data sets presents an enormous opportunity—but the speed of innovative advancements in an already highly regulated industry presents a patchwork of legal and regulatory guardrails that can be difficult to navigate.

We explore some of the emerging AI-powered tools in Canada's life sciences market and the legal considerations that stakeholders in these fields should keep top of mind.

An evolving approach to regulating AI-driven medical devices

As medical device manufacturers are finding new ways to make the most of the vast amount of patient data routinely collected in the delivery of health care, we are seeing an increase in AI-driven devices capable of learning from real-world experiences and outputting diagnoses and treatment plans based on patient-specific metrics.

To learn and predict, AI takes data from medical imaging results, diagnostic blood and urine test results, genetic markers, patient demographics and patient outcomes; this offers up endless diagnostic and treatment possibilities but also presents nuanced legal obligations.

Pre-market review and licensing by Health Canada is a key requirement for most medical devices (Class II-IV devices); however, a challenge with licensing AI-based medical devices is that the products' algorithms are often adaptive rather than static. This means the device that Health Canada initially reviews and approves will continually change after its market release through iterative software modifications. Health Canada must, therefore, balance the need to identify emerging risks associated with these products versus the impracticality of repeatedly re-evaluating products for modifications post-market.

For those who build AI-driven medical devices, it is important to understand that Health Canada's approach to their regulation is evolving[1]. There is an expectation that medical device manufacturers may face longer licence review times and more onerous post-market obligations where novel AI processes are involved. Device manufacturers should continue to monitor Health Canada's position on this topic and consider requesting pre-submission meetings with Health Canada whenever emerging AI technologies are utilized.

Chatbots at a regulatory crossroads

Creating efficiencies in healthcare delivery will always be a focus of innovation in the industry, which has led to the development of tools that can replace non-essential, routine communications. AI-powered chatbots continue to evolve, delivering more precise, adapted communications to patients as they become more integrated into the healthcare system.

Chatbots pose an interesting regulatory issue, with ongoing discussions as to whether they should be categorized as medical devices. If classified as a medical device, then the software must obtain licensing or pre-market authorization depending on its specific characteristics. Based on Health Canada's guidance[2], software that is only intended to support a healthcare professional or patient/caregiver in making decisions about the prevention, diagnosis or treatment of a disease or condition might not be considered a medical device—as long as it doesn't replace the clinical judgment of a health care professional.

On this basis, several chatbots operating today are without medical device regulatory oversight, and there is a grey area in which new chatbots can be launched. However, as advances are made and the line between supporting and replacing a clinical decision is blurred, chatbot creators will likely see more regulations come into play. As with those building AI-driven medical devices, chatbot companies should ensure they pay close attention to Health Canada's decisions and seek clarification as and when needed.

AI's role in drug discovery

AI is considered by many as a revolutionary force in drug discovery. In Canada, the federal government has taken several steps to further streamline the use of AI in this area, including a $49 million investment through the Strategic Innovation Fund for the Conscience Open Science Drug Discovery Network[3].

Developments in this field aim to lessen potential drug candidates' failure across each stage of the drug investigation process, due to the pathway from bench to clinical testing being a lengthy, expensive and risky endeavor. With AI as a tool, drug discovery can take substantially less time, meaning more potential treatments get into clinical trials with

less upfront investment cost.

AI can be trained on the large data sets available to help identify the biological targets that cause disease or its symptoms, screening for molecules or protein fragments that may interact with those targets. Key properties of a target that would make it a suitable treatment can be predicted and modeled with AI tools, reducing the amount of physical testing in the discovery stage. With less time spent in discovery, pharmaceutical companies can explore more targets, bring more leads into clinical trials and develop therapies at a lower cost—which may translate into a lower price tag at market entry.

Intellectual property considerations are important in any drug discovery program, and this can be amplified when AI tools are used. Third-party ownership rights in the data used to train an AI system could create copyright and other issues with the resulting outputs, so it is important to consider conditions and restrictions on data usage when public or non-internal sources are utilized.

Clinical trials can use AI to streamline tasks

Following the drug discovery process, life sciences companies are also using AI technologies to test product candidates and streamline various clinical research activities during human trials. This reduces costs, makes trials safer and accelerates time to market. For example, predictive modeling technologies are advancing study recruitment by identifying patient populations most likely to benefit from an investigational product. AI is also being leveraged to monitor study subjects in real-time, including during decentralized clinical trials where patients are evaluated remotely. It is also being used to analyze large amounts of clinical study data to identify patterns that might otherwise be overlooked by human researchers.

Notably, AI is being increasingly applied in clinical trials to supplement the manual work performed by live research staff. For example, AI-powered virtual assistants can provide patients with initial trial information, answers to questions and preliminary screening. In a study design, language models can assist with drafting initial research protocols.

Given the patient risks involved in clinical trial activities, interactions with human research staff are typically considered essential to ensure that informed consent is properly obtained from study subjects and to appropriately monitor adverse events, protect patient privacy and maintain data integrity. The systems used to collect and manage patient data must be transparent, have human oversight and monitoring, and follow a process for fairness and equity to avoid discriminatory outcomes[4]. This means that drug companies must have clear protocols in place to meet these requirements each step of the way. Management of these issues should be top of mind when clinical research staff roles are being replaced or supplemented with AI technologies.

Regulatory next steps for AI in healthcare

Technological advances are accelerating the pace of change in health care, specifically for personalized care. Anticipating this, in 2019, Health Canada amended the *Food and Drugs Act* to introduce a structure for the regulation of advanced therapeutic products. With this in place, Health Canada can propose new regulations, guidance and requirements as innovations emerge.

As a follow-up to those amendments, Health Canada is developing a framework for the regulation of “advanced therapeutic products” meant to address drugs and/or devices that are so complex or distinct from their traditional counterparts that they are not contemplated by current regulations.

Machine learning-enabled devices were the first area identified by Health Canada as requiring unique and flexible oversight, which led to the drafting of “Pre-market guidance for machine learning-enabled medical devices”[5]. In the coming years, we can expect to see more custom guidance as Health Canada and other regulators evolve their approaches to assessing novel therapies and support systems.

FOOTNOTES

1. Notably in September 2023, Health Canada released its “Draft guidance document: Pre-market guidance for machine learning-enabled medical devices”.
2. See “Software as a Medical Device (SaMD): Definition and Classification”: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/application-information/guidance-documents/software-medical-device-guidance-document.html#a2.1
3. Government of Canada invests in new open science drug discovery network: https://www.newswire.ca/news-releases/government-of-canada-invests-in-new-open-science-drug-discovery-network-851811859.html
4. https://ised-isde.canada.ca/site/innovation-better-canada/en/artificial-intelligence-and-data-act-aida-companion-document#s8
5. https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/application-information/guidance-documents/pre-market-guidance-machine-learning-enabled-medical-devices.html

To discuss these issues, please contact the author(s).